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APPLICATION NUMBER 674311	FILING DATE 07/01/96	FIRST NAMED APPLICANT OLUPADE	ATTORNEY DOCKET NO. 0 ARSB:509
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18M2/1110

EXAMINER

ATZEL, A

ART UNIT PAPER NUMBER

1307

8

DATE MAILED: 11/10/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8-29-97
☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1, 7, 8, 10-25, 34-38 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1, 7, 8, 10-25, 34-38 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of Reference Cited, PTO-892
Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
Interview Summary, PTO-413
Notice of Draftsperson's Patent Drawing Review, PTO-948
Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

DETAILED ACTION

The amendment filed 29 August 1997 has been entered. The amendments and arguments have been duly considered by the examiner. Rejections not reiterated from the last office action are hereby withdrawn. The following rejections are either reiterated or necessitated by amendment.

Claim Rejections - 35 USC § 112

Claims 7, 8, 10-12, 36 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7 and those depending therefrom, the meaning of "high stringency" is unclear because terms of stringency are relative terms rather than absolute terms. Applicant has pointed to specification page 89, line 25 to provide support for "high stringency"; however, when used in the claims, the term must be given the broadest reasonable interpretation. If applicant intends to define the term "high stringency" to mean conditions of 0.1xSSC, 1% SDS, 65°C for 45 minutes, it is suggested to reproduce such language in the claims.

In claims 36 and 38, the meaning of "T98G" is unclear in that no specific characteristics of the claimed chemical are given besides that it is DNA. Applicant points out specification pages 52, 53, 56 to clarify T98G, but from the specification it seems that T98G is not DNA, but is a designation for a cell line. Therefore, it is not clear how a DNA segment can "comprise" a cell line.

Claims 34 and 35 are rejected under 35 USC fourth paragraph for failing to further limit claim 1. As amended, these claims depend from claim 1 and merely recite properties inherent to the DNA segment of claim 1. Furthermore, these claims are misleading in that they imply that MTAP has the tumor suppressor properties, when it is probably other genes (e.g. p16 also known as MTS1) that have tumor suppressor function which would be present in a DNA segment that "comprises" SEQ ID NO:1 (e.g. chromosome 9p locus). The examiner interprets claim 1 to be a DNA segment comprising the MTAP gene depicted as SEQ ID NO:1, which includes isolated chromosome 9p fragments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 8, 10-12, 15, 17, 18, 20, 21, 34 and 35 are rejected under 35 USC § 102(b) as being anticipated by Kamb et al. (1994). Kamb et al. disclose tumor suppressor gene MTS1 which maps to 9p21-22. The cosmid that contains MTS1 in Kamb et al. also contains MTAP as the two genes are tightly linked, thus the DNA segment in the cosmid "comprises" SEQ ID NO:1 and therefore the MTAP gene.

Claims 1, 7, 8, 10-12, 15, 18, 20, 21, 34-36, 38 are rejected under 35 USC § 102(a) as being clearly anticipated by Porterfield et al. (1994). Porterfield et al. disclose a tumor suppressor gene that maps to chromosome 9p21, and methods of distinguishing tumor types by comparing 9p deletions between tumors identical to the claimed invention. In particular, on page 399, this reference reports that a 1400-kb NotI chromosome 9p fragment is known to contain the MTAP gene. Thus this DNA segment is isolated and inherently contained SEQ ID NO:1.

Claims 1-12, 15-18, 20-25, 34-38 are rejected under 35 USC § 102(b) as being clearly anticipated by Bohlander et al. (1994). Bohlander discloses a chromosome fragment comprising the MTAP gene, kits and methods of use identical to the claimed invention (see figure 4) because chromosome segments that comprise the MTAP gene inherently comprise SEQ ID NO:1.

Claims 1-12, 15-18, 20-25, 34-38 are rejected under 35 USC § 102(a) as being clearly anticipated by Dreyling et al. (Cancer Res. 1995). Dreyling et al. disclose DNA segments comprising the MTAP gene and isolated region designated T98G, and kits and methods of use. See figure 1.

Claims 1-13, 15-25, 34, 35, 37, 38 are rejected under 35 USC § 102(a) as being clearly anticipated by Olopade et al. (PNAS 1995). Olopade et al. disclose MTAP cDNA, gene and isolated region designated T98G, and kits and methods of use including Northern blots. This rejection is maintained as applicant has not submitted a Katz declaration or antedated or rebutted the teachings in this reference.

Claims 1-12, 15-18, 20-25, 34-38 are rejected under 35 USC § 102(b) as being clearly anticipated by Nobori et al. (Nature 1994). Nobori et al. disclose MTAP cDNA, gene and isolated region designated T98G, and kits and methods of use.

Claims 26-33 are rejected under 35 USC § 102(b) as being clearly anticipated by Nobori et al. (Cancer Res. 1991) or by Nobori et al. (Cancer Res. 1993). Nobori et al. disclose methods, kits and antibodies that bind to MTAP that are linked to alkaline phosphatase through a secondary antibody (Nobori et al., 1991) or linked to an I-125 label via protein A.

Claims 37 and 38 are rejected under 35 USC § 102(b) as being clearly anticipated by Scaletti et al. (1987). Scaletti et al. disclose methods of distinguishing tumor types by comparing chromosome 9p patterns between tumor types.

Remarks

Applicant argues that Dreyling et al. detect CDKN2 region of chromosome 9p and therefore does not anticipate claims. This is not persuasive because MTAP is in the region of CDKN2 on chromosome 9p21. Figure 1 of this reference illustrates numerous isolated DNA segments that comprise MTAP and inherently SEQ ID NO:1.

Similarly, Bohlander et al. isolate by microdissection and clone DNA segments from 9p21-p22 that comprise the MTAP gene. The argument that the relative map position of MTAP is uncertain is not relevant because this does not negate the isolation of the DNA segments.

Rebuttal to the Nobori et al. (1994) reference is not persuasive because as specifically stated on page 753, column 2 second paragraph after the abstract, MTAP cDNA was isolated.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Serial Number: 08/674311
Art Unit: 1807

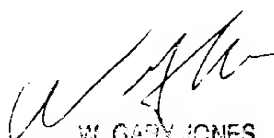
Page 5

Inquiries concerning this communication should be directed to Amy Atzel at: voice: (703) 308-0208

FAX FOR OFFICIAL RESPONSES: 703-305-3014

If attempts to contact the examiner are unsuccessful please call Supervisory Patent Examiner Gary Jones at (703) 308-1152.

Amy Atzel, Ph.D.
November 6, 1997


W. GARY JONES
SUPERVISORY PATENT EXAMINER
GROUP 1800

11/7/97